IN THE UNITED DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

UNITED STATES OF AMERICA

v. : Criminal No.: 1:14-CR-256

:

NIBEDITA MOHANTY, M.D.

:

Defendant.

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY

COMES NOW the Accused, Nibedita Mohanty, M.D., by counsel, and moves this Court, pursuant to Federal Rules of Evidence 104(a), 702, and 703, for entry of an Order excluding the expert opinion testimony of (1) Dr. Michael A. Ashburn and (2) Dr. Stuart J. Finkelstein. In support thereof, Dr. Mohanty states the following:

INTRODUCTION

On December 26, 2014, the last day due pursuant to the discovery order, the government filed the Government's Notice of Intent to Use Expert Testimony (the "Notice"), indicating its intent to use the expert testimony of Dr. Michael A. Ashburn and Dr. Stuart J. Finkelstein, among other designated experts, in its case in chief and/or in rebuttal. While the reports of these two designated experts, particularly that of Dr. Ashburn, go into much detail regarding the history and treatment of each identified patient, they fail to meet the standard for the admissibility of expert opinion testimony. Accordingly, Dr. Mohanty moves this Court to exclude the expert testimony of Dr. Ashburn and Dr. Finkelstein. In the alternative, if the Court does not exclude their testimony, the Movant requests a *Daubert* hearing regarding the admissibility of their testimony.

ARGUMENT¹

I. <u>Dr. Ashburn</u>

A. Facts

In its Notice, after outlining the many credentials of Dr. Ashburn, the government states that it expects that:

Dr. Ashburn will testify that the defendant's actions relating to the charged counts in the indictment were not for legitimate medical purposes in the usual course of her professional medical practice, were beyond the bounds of medical practice, or both. We further expect that Dr. Ashburn will testify that his opinions and conclusions are based on his training and experience and on his review of the defendant's records and prescription practices for specific patients referenced in the indictment.

The Notice further represents that the government expects that Dr. Ashburn "will testify that the defendant's actions fell below the standard of medical practice in numerous respects"

Attachment 1A to the Notice contains Dr. Ashburn's expert report providing his opinions on Dr. Mohanty's treatment of her chronic pain patients. In approximately 194 pages, Dr. Ashburn's report details in narrative form and in chronological order the various office visits by the named patients, the prescriptions issued on each visit, increases and decreases in prescribed dosages, patient responses to treatment, the different combinations of medications prescribed, notes and correspondence in patient files, early refills of medications, requests for reports from the Prescription Monitoring Program ("PMP") and the contents of those reports, indications of abuse or diversion and whether or not they were addressed, statements made by Dr. Mohanty to the

A copy of the government's expert designations and reports will be provided to chambers.

Department of Health Professions or to investigators, and other aspects of Dr. Mohanty's care for each identified patient. After a lengthy and detailed narrative for each patient, Dr. Ashburn provides the following conclusions in nearly identical language for each patient:

- "Based on available information, the prescribing of opioids to [patient] was not for a legitimate medical purpose."
- "The prescribing of opioids was not based on sound clinical judgment."
- "The prescribing of opioids was not based on current best clinical practices."
- "The prescribing was not appropriately documented, and was not of any demonstrable benefit to the patient."
- "Based on available information, the prescribing of opioids by Dr. Mohanty to [patient] was not within the usual course of professional practice."
- It "does not appear that a legitimate physician-patient relationship existed."
- "The prescribing was not appropriate to the identified diagnoses."
- "The prescribing was not accompanied by careful follow-up monitoring of the patient's response to the prescribed medication."
- "There was no evidence of any monitoring for the safe use of the prescribed medications, and early refills of opioids were the norm rather than the exception"
- "The prescribing was not adjusted as necessary."
- "No referrals . . . were ever made" or referrals were not followed up on.

The above language, or slight variations of it, is in the conclusion set forth for each patient, despite the wide variations in the clinical histories, documented illnesses, prescriptions and other treatments, responses to treatments, referrals to specialists, indications of abuse or lack thereof, number and frequency of urine tests or other forms of monitoring of safe use, number and frequency of requests for PMP reports, social histories, and other differences between the twenty-two patients addressed in the report. Indeed, Dr. Ashburn's conclusions simply track the language of the Model Guidelines published by the Federation of State Medical Boards of the United States, as outlined in the "Criteria used in this review" section of his report.

B. Argument

Dr. Ashburn's expert opinion testimony should be excluded pursuant to Rules 104(a), 702, and 703 of the Federal Rules of Evidence for several reasons. *First*, Dr. Ashburn fails to apply "reliable principles and methods" to his individual analysis of each patient's file as required by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), and the 2000 amendments to Rule 702. *Second*, to the extent that Dr. Ashburn's report attempts to outline the standards by which he reviewed Dr. Mohanty's files, Dr. Ashburn relies on incorrect standards and methodologies and fails to distinguish between the civil standard of medical malpractice and the applicable criminal standard. *Third*, Dr. Ashburn improperly applies a national standard of medical practice in reviewing Dr. Mohanty's files and fails to consider—let alone address—the local standard of care as required by the case law. *Finally*, Dr. Ashburn's testimony should be excluded because it will not assist the trier of fact and is more prejudicial than probative.

1. Dr. Ashburn Fails to Apply Reliable Principles and Methods to His Review of Individual Patient Files

In his report, Dr. Ashburn delves deeply into each patient's file to provide a detailed chronology of each patient's care at the hands of Dr. Mohanty, followed by a litany of conclusory statements lifted almost verbatim from the Model Guidelines of the Federation of State Medical Boards. Conspicuously missing between those two steps, however, is a reasoned explanation of the applicable principles and methods relied upon by Dr. Ashburn to reach those conclusions, as well as how those principles and methods lead to his conclusions.

As the proponent, the government must demonstrate that its expert's testimony satisfies Rules 702 and 403. United States v. Lester, 234 F. Supp. 2d 595, 598 (E.D. Va. 2002). From the outset, the government's Notice sets the tone for Dr. Ashburn's conclusory analysis. In describing the basis for Dr. Ashburn's opinions, the Notice states: "We further expect that Dr. Ashburn will testify that his opinions and conclusions are based on his training and experience and on his review of the defendant's records and prescription practices for specific patients referenced in the indictment." (emphasis added). In his report, Dr. Ashburn provides four pages in which he describes the criteria used in his review. That section relies heavily on the Model Guidelines, from which Dr. Ashburn lifts the majority of his conclusions on what he deems to be improper practice of medicine. Yet the Model Guidelines themselves expressly state: "This policy is not meant to constrain or dictate medical decision-making" and that "[t]he Model Policy is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations." 2004 Model Guidelines, available at http://goo.gl/ZXzQqr.

In any case, with the exception of the four-page discussion of the criteria purportedly applied, Dr. Ashburn fails to actually apply any standards, principles, or methodology to his review of each patient's file. Instead, he provides a narrative followed by damning conclusions. Those conclusions—the government's introduction to Dr. Ashburn's report explains—are based on his review of patient files and "his training and experience." But this is precisely the type of opinion testimony that *Daubert* and its progeny prohibit. The Committee Note to the 2000 Amendments of Rule 702 expressly says that "[i]f the witness is relying solely or primarily on experience, then the witness

must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply 'taking the expert's word for it." In light of the wide variations between the different patient files reviewed by Dr. Ashburn as discussed above, the fact that Dr. Ashburn's conclusions are nearly identical for all of the reviewed patient files raises serious questions about whether Dr. Ashburn applied any standards or principles to his review of each file, as well as how he reached the conclusions that he did—aside from his "experience and training." See John Thornton, The General Assumptions and Rationale of Forensic Identification, in David L. Faigman, David H. Kaye, Michael J. Saks, Joseph Sanders, 3 Modern Scientific Evidence: The Law and Science of Expert Testimony (2012 ed.) § 29:21 ("Many witnesses have learned to invoke experience as a means of circumventing the responsibility of supporting an opinion with hard facts. For the witness, it eases cross-examination. But it also removes the scientific basis for the opinion.").

Daubert requires this Court to determine "whether the reasoning or methodology underlying the testimony is . . . valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 592-93 (emphasis); see also Kumho Tire Co., 526 U.S. at 141 (expanding Daubert's holding to expertise deemed "technical" or "specialized knowledge" under Rule 702). Moreover, the amended Rule 702 imposes a higher standard on the admissibility of expert opinion testimony:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to

determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702 (emphasis added). This "newly-expanded rule goes further than *Kumho* to 'provide . . . some general standards that the trial court *must* use to assess the reliability and helpfulness of proffered expert testimony." *Rudd v. General Motors Corp.*, 127 F. Supp. 2d 1330, 1336 (M.D. Ala. 2001) (emphasis in original).

While the inquiry into 'reliable principles and methods' has been a familiar feature of admissibility analysis under *Daubert*, the new Rule 702 appears to require a trial judge to make an evaluation that delves more into the facts than was recommended in *Daubert*, including as the rule does an inquiry into the sufficiency of the testimony's basis ('the testimony is based upon sufficient facts or data') and an inquiry into the application of a methodology to the facts ('the witness has applied the principles and methods reliably to the facts of the case') Neither of these two latter questions that are now mandatory under the new rule--the inquiries into the sufficiency of the testimony's basis and the reliability of the methodology's application-were expressly part of the formal admissibility analysis under *Daubert*.

Id. at 1336 (emphasis added); see also United States v. Nacchio, 555 F.3d 1234, 1241 (10th Cir. 2009) (en banc) (under amended Rule 702 and Daubert, "[r]eliability questions may concern the expert's data, method, or his application of the method to the data The party offering the expert must show that the method employed by the expert . . . is scientifically sound and that the opinion is based on facts which satisfy Rule 702's reliability requirements [A]ny step that renders the expert's analysis unreliable . . . renders the expert's testimony inadmissible. This is true whether the step

completely changes a reliable methodology or merely misapplies that methodology.") (internal quotations and citations omitted).

Applying these principles to Dr. Ashburn's proffered testimony unavoidably leads to the conclusion that it is inadmissible under *Daubert* and the amended Rule 702. Even if Dr. Ashburn's report is generously read to include an explanation of the principles and methods applicable to his review in the "Criteria" section of his report, nowhere in his report does he actually *apply* those principles and methods to the facts relevant to each patient. As such, his proffered testimony lacks an essential element of expert opinion testimony—reliable application of his methodology to the relevant facts. Indeed, given the absence of that crucial step, it is not possible for this Court to properly conduct its important gatekeeping function in reviewing Dr. Ashburn's proposed testimony. Accordingly, his testimony is inadmissible and should be excluded.

2. The Report Applies Incorrect Standards

To the extent that Dr. Ashburn's report attempts to define the relevant standard applicable to his review of Dr. Mohanty's care, Dr. Ashburn cites to incorrect standards and confuses the civil medical malpractice standard with the applicable criminal standard. In its introduction to his testimony, the Notice states that the government expects "that Dr. Ashburn will testify that the defendant's actions *fell below the standard of medical practice* in numerous respects" (emphasis added). In defining what that standard is in the "Criteria" section of his report, Dr. Ashburn relies on the 2013 Model Guidelines as the rubric for determining whether Dr. Mohanty's actions "were not for legitimate medical purposes in the usual course of [her] professional medical practice or beyond the bounds of medical practice" as required for a violation of the Controlled

Substances Act ("CSA"). See United States v. Tran Trong Cuong, 18 F.3d 1132, 1141 (4th Cir. 1994).

But the Model Guidelines were not intended to—nor do they in fact—mirror the standards of criminal culpability for licensed physicians under the CSA. Rather, the Model Guidelines state the intent of the Guidelines as follows: "The policy thus is intended to encourage physicians to be knowledgeable about best clinical practices as regards the prescribing of opioids and be aware of associated risks," and that "[t]he revised Model Policy makes it clear that the state medical board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practice." 2013 Model Guidelines, available http://goo.gl/xw4fBj. In other words, the standards set by the Model Guidelines are intended to set forth the "accepted best clinical practices," an aspirational standard that is far higher than that required to avoid criminal liability for licensed physicians under the CSA. "For a controlled substance prescription to be effective, the prescription 'must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.' United States v. Mackay, 715 F.3d 807, 814 (10th Cir. 2013) (quoting 21 C.F.R. § 1306.04(a)). While the Model Guidelines provide instructions that would also allow physicians to avoid censure under the CSA, they go above and beyond ensuring that controlled substance prescriptions are issued for a "legitimate medical purpose in the usual course of professional practice" and within "the bounds of medical practice" to also ensuring that physicians comply with the "current best clinical practices." Thus, it is no surprise that Dr. Ashburn concludes for each

patient that Dr. Mohanty failed to comply with the "current best clinical practices," a much higher standard that is not relevant to the present case.

The Fourth Circuit has held that "there are no specific quidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts." United States v. Boccone, 556 F. App'x 215, 228 (4th Cir. 2014) (emphasis added) (internal quotations and citations omitted). Dr. Ashburn's reliance on the Model Guidelines seeks to improperly shoehorn what is acceptable "professional practice" under the CSA into the aspirational guidelines provided by a national association of state medical boards seeking to establish "current best clinical practices." That type of analysis imposes an unreasonably rigid standard that contradicts the case law on what constitutes a violation of the CSA. See Gonzales v. Oregon, 546 U.S. 243, 258 (2006) ("All would agree, we should think, that the statutory phrase 'legitimate medical purpose' is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense."); United States v. Collier, 478 F.2d 268, 272 (5th Cir. 1973) ("In making a medical judgment concerning the right treatment for an individual patient, physicians require a certain latitude of available options.").

Moreover, Dr. Ashburn's analysis repeatedly confuses the civil standard of medical malpractice with the much higher standard of criminal conduct. The law is clear that proof of medical malpractice is insufficient to establish culpability under the CSA. See *United States v. Smith*, 573 F.3d 639, 649 (8th Cir. 2009) ("It is true that courts

have recognized a danger in confusing medical-malpractice and § 841 standards."); Tran Trong Cuong, 18 F.3d at 1137-38 ("A criminal prosecution requires more [than proof of negligence] – that is, proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice"). Yet Dr. Ashburn peppers his analysis with statements such as "the prescribing was not based on sound clinical judgment," "the prescribing was not based on current best clinical practices," "the prescribing was not of any demonstrable benefit to the patient," and "the prescribing was not appropriate to the identified diagnoses." These statements suggest a lower standard of criminal culpability based on the civil standard of negligence or malpractice.

3. The Report Improperly Applies a National Standard of Medical Practice

In addition to citing to incorrect standards and confusing the civil and criminal standards of liability, Dr. Ashburn's report improperly applies a national standard of medical practice and fails to address or evaluate the local standard of practice applicable to the kind and size of medical practice managed by a local, small office practitioner physician in Stafford County. Dr. Ashburn's credentials and background are quite impressive as evident from his twenty-four page resume. But in reviewing Dr. Mohanty's files, Dr. Ashburn fails to appreciate or address the significant differences between an eleven-physician-strong specialized pain management center staffed with leading physicians in the field with distinguished credentials and hospital affiliations operating in a large city, versus a primary care physician operating in Stafford County, Virginia.

In Gonzales v. Oregon, the Supreme Court recognized important limitations on the federal government's regulation of medical practice pursuant to the CSA, principal among them the idea that the CSA "manifests no intent to regulate the practice of medicine generally." 546 U.S. at 269. Indeed, "[t]he CSA's substantive provisions and their arrangement undermine [the] assertion of an expansive federal authority to regulate medicine." Id. at 273. As a corollary of this principle, courts have recognized that "[t]he determination of what constitutes a legitimate medical practice or purpose traditionally has been left to the individual states. State statutes, state medical boards, and state regulations control the practice of medicine. The CSA was never intended, and the USDOJ and DEA were never authorized, to establish a national medical practice or act as a national medical board." Oregon v. Ashcroft, 192 F. Supp. 2d 1077, 1092 (D. Or. 2002), aff'd Gonzales v. Oregon, 546 U.S. 243 (2006). Put otherwise, there is no national standard applicable to determining whether a physician has acted "outside the bounds of professional practice" or whether prescriptions were issued for "a legitimate medical purpose." See United States v. Joseph, 709 F.3d 1082, 1095 (11th Cir. 2013) (acknowledging that a jury instruction applying a national standard of care would be erroneous in the aftermath of *Gonzales v. Oregon*).

Despite the foregoing, Dr. Ashburn's proposed testimony would apply a national standard of what is deemed to be legitimate medical practice with no discussion or application of variations between the national standard and local standard of medical practice. For example, Dr. Ashburn fails to consider or discuss the fact that Virginia law expressly authorizes physicians to prescribe opioids above the generally recommended amounts if issued in good faith and in compliance with the relevant statute. See Virginia

Code § 54.1-2971.01. He likewise fails to address the differences between a practice managed by pain specialists and one run by a general practitioner or internist in evaluating the document retention and record keeping practices of Dr. Mohanty. In doing so, Dr. Ashburn fails to consider the local standard of care and improperly subjects Dr. Mohanty's practice to a national standard without consideration of variations based on the size and location of a medical practice.

4. Dr. Ashburn's Testimony Will Not Assist the Trier of Fact And Is More Prejudicial Than Probative

Finally, Dr. Ashburn's testimony should be excluded because it will not assist the trier of fact and is more prejudicial than probative. As the Supreme Court has recognized, "[t]estimony emanating from the depth and scope of specialized knowledge is very impressive to a jury. The same testimony from another source can have less effect." *Ake v. Oklahoma*, 470 U.S. 68, 82 n.7 (1985) (citation omitted). Consequently, Rule 702 requires that expert opinion testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. "Relevant expert testimony must logically advance a material aspect of the case, and be sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *United States v. Garcia*, 635 F.3d 472, 476 (10th Cir. 2011) (citations and internal quotations omitted).

As discussed above, Dr. Ashburn's testimony fails to apply any standard or methodology to his review of individual patient files. As such, it fails to "advance a material aspect of the case" or to "be sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Id.* Rather, the government seeks to present Dr. Ashburn's conclusions as to the ultimate issues in dispute after rote recitations of

patient histories, and to base those conclusions on Dr. Ashburn's experience and knowledge rather than on a reasoned application of reliable principles and methods. That is precisely the type of testimony that fails to assist the trier of fact in a case like this. It is also extremely prejudicial given the impact of expert testimony on jurors and the significant weight given such testimony. Dr. Ashburn's testimony also fails to assist the trier of fact because, as discussed above, no specific guidelines govern what is outside the bounds of professional practice. Thus, expert opinion testimony that simply lifts from Model Guidelines that provide specific guidelines that do not govern the question of criminal culpability in this case is of no help to the trier of fact.

Accordingly, Dr. Ashburn's proposed testimony should be excluded.

II. Dr. Finkelstein

In addition to Dr. Ashburn's proposed testimony, the government has noticed its intent to offer the expert opinion testimony of Dr. Stuart Finkelstein regarding patients Timothy Wade, Drew Carrigan, and Lindsey Ramey. Because Dr. Finkelstein's proposed testimony suffers from similar defects as Dr. Ashburn's testimony, it should similarly be excluded.

In providing the basis for his testimony, Dr. Finkelstein simple states:

I have used the following references in forming my opinions: the TIPS 40 guidelines for the use of buprenorphine, buprenorphine and office-based practice from SAMHSA, clinical guidelines for the use of buprenorphine and the treatment of opiate addiction, DATA 2000, eight-hour review course offered by the American Society of Addiction Medicine, and the practice tool kit provided by Reckitt Benckiser.

Nowhere in his report does Dr. Finkelstein set forth the principles, standards, or methodology applied in reviewing Dr. Mohanty's patient files. Nor does he explain what

the above-cited resources provide or how those resources lead to his ultimate conclusions regarding Dr. Mohanty's treatment of Drew Carrigan, Timothy Wade, and Lindsey Ramey. Instead, Dr. Finkelstein provides a chronology of what each patient's file reflects with occasional comments on what is or is not appropriate treatment or prescribing. After outlining "red flag behaviors," Dr. Finkelstein concludes that "[t]here was a deviation from standard of care" without explaining what that standard of care is. He then proceeds to conclude that Dr. Mohanty's prescribing was not within the bounds of legitimate medical practice, her documentation was inadequate and "not to the standard of community care," and "was not for a legitimate medical purpose and was not within the usual course of professional practice." Again, the "standard of community care" is nowhere defined in his report. After evaluating each patient as described above, Dr. Finkelstein identifies six alleged deviations from "the Standards of Care." What those standards are remains a mystery.

Like Dr. Ashburn's report, Dr. Finkelstein's proposed testimony is not based on reliable principles and methods. Nor does it *apply* any principles and methods to the patient files reviewed to reach the conclusions set forth in the report. Even more so than Dr. Ashburn, Dr. Finkelstein fails to set forth the standards relied upon in determining the legitimacy of Dr. Mohanty's prescriptions and whether she acted in the usual course of professional practice. A one-paragraph string citation to resources on pain management is not the type of "reliable principles and methods" required by *Daubert* and Rule 702. See Fed. R. Evid. 702 (requiring that "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and

methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.").

Similar to Dr. Ashburn's report, Dr. Finkelstein's report also confuses the applicable criminal standard under the CSA with the lower medical malpractice standard and fails to adequately explain the "standard of community care" or "standard of care" he frequently cites. Indeed, his report appears to apply a negligence standard of care throughout. For example, Dr. Finkelstein states in his analysis for Timothy Wade and Drew Carrigan: "Dr. Mohanty often prescribed Subutex and Suboxone p.o. rather than sublingual, which creates a question as to whether Dr. Mohanty was knowledgeable about the use of buprenorphine in the first place." (emphasis added). Likewise, his conclusion that Dr. Mohanty's documentation was "inadequate" suggests a negligence standard. This type of testimony, as discussed *supra*, misapplies the relevant standard necessary for criminal liability under the CSA. It also tends to confuse and prejudice the trier of fact rather than assisting the trier of fact in any meaningful way. Finally, like Dr. Ashburn, Dr. Finkelstein appears to apply a national standard of care and fails to consider the local standard of care applicable to Dr. Mohanty's practice. Accordingly, Dr. Finkelstein's proposed expert opinion testimony should be excluded.

CONCLUSION

For the foregoing reasons, the proposed expert opinion testimony of Dr. Ashburn and Dr. Finkelstein should be excluded at trial. In the alternative, if the Court does not exclude their testimony, the Movant respectfully requests a *Daubert* hearing regarding the testimony of these two experts.

Respectfully Submitted, NIBEDITA MOHANTY, M.D.

GREENSPUN SHAPIRO PC

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CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of January, 2015, the foregoing document was filed with the Court via CM/ECF, and a copy provided via electronic mail to the following:

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